



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

September 2, 2003

CONSENT DECREE CORRESPONDENCE

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Alan McCurry
Executive Vice President and CEO
Biomedical Services
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

RE: United States v. American National Red Cross, Civil Action No. 93-0949 (JGP)

Dear Mr. McCurry:

Paragraph IV.B.1. of the Amended Consent Decree of Permanent Injunction, Civil No. 93-0949 (JGP), entered April 15, 2003 (Decree), requires the American National Red Cross (ARC) to establish and submit to the Food and Drug Administration (FDA) within 90 days after entry of the Decree a Problem Management standard operating procedure (SOP) to detect, investigate, evaluate, correct, and monitor all problems, trends, and systemic problems. Paragraph VI of the Decree requires FDA to advise ARC whether the SOP appears to be adequate to bring ARC into compliance with the law and the Decree. FDA advised ARC in an Adverse Determination Letter dated July 22, 2003, that the SOP is in many respects inadequate to bring ARC into compliance with the law and the Decree. In that letter, FDA ordered ARC to revise the SOP and advised ARC that pursuant to Paragraph IX, it intends to fine ARC up to \$10,000 for each day from the date ARC submitted the SOP until the date ARC submits to FDA a plan to revise the SOP. FDA received ARC's SOP on June 6, 2003, and ARC's plan to revise the SOP on August 6, 2003.

As stated in its July 22, 2003 letter to ARC, FDA regards the Problem Management SOP as a first and indispensable step to enable ARC to come into compliance with current good manufacturing practice. However, despite the very specific requirements set forth in the Decree and the fact that FDA repeatedly brought the deficiencies to be addressed by the SOP to ARC's attention in past years, ARC submitted an SOP that is not significantly different from its existing inadequate SOP and that fails to incorporate many of the required elements. For example, the Decree requires that ARC investigate, correct, and prevent all problems; yet, ARC's SOP clearly ignored that requirement, instead only requiring investigation of "certain" problems. That ARC submitted such an inadequate SOP raises concerns about whether this SOP was reviewed by ARC management and consultants. For the foregoing reasons, among others, FDA believes that a \$10,000 per diem fine is warranted.

However, FDA has considered that ARC is under the leadership of a new President and Chief Executive Officer and that this failure to comply with the Decree, while egregious, appears to be ARC's first known violation after the April 15, 2003 entry date. Based on those two factors, FDA is assessing a \$8500 per diem fine for the period June 6, 2003, through August 5, 2003. The total amount of the fine is \$518,500.

Paragraph XX of the Decree states that ARC may seek administrative review of the amount of any penalty imposed by FDA under the Decree. If ARC intends to seek such review, it must submit its request in writing within 10 calendar days from ARC's receipt of this letter to the FDA Director, Baltimore District, in accordance with Paragraph V.

In accordance with paragraph IX.F.7. of the Decree, all payments made under this Decree must be payable to United States Treasury and must be made by electronic transfer to the Treasury of the United States in accordance with the attached instructions which have been provided by the Office of Consumer Litigation, Civil Division, United States Department of Justice. ARC must, contemporaneous with the electronic transfer, provide written notification to the FDA Director, Baltimore District and the Associate Commissioner of Regulatory Affairs that payment has been made. Payment is due within 30 calendar days of ARC's receipt of this letter.

If you have any questions regarding this response, please contact me at (410) 779-5424.

Sincerely yours,



Lee Bowers
Director, Baltimore District

cc: Marsha Johnson Evans
President & CEO
American National Red Cross
430 17th Street, N.W.
Washington, D.C. 20006

Mary Elcano
General Counsel
American National Red Cross
430 17th Street, N.W.
Washington, D.C. 20006

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David T. McLaughlin
Chairman, Board of Governors
American National Red Cross
430 17th Street, N.W.
Washington, D.C. 20006